MAY 12 2000

510(k) Summary of Safety and Effectiveness

Submitted By: K000950

Angelika Albrecht
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Germany
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Date 2000-03-14

Device:

Trade Name: Embryo Transfer Catheter Set
Proposed Classification Name: Assisted Reproduction Catheters
Class II 85 MQF

Predicate Device:

Trade name:	Class	CFR Referece	Procode
Embryo Transfer Catheters/Sets	II	21CFR 884.6110	85 MQF

Classification name: Assisted reproduction catheters

Manufacturer: Cook Ob/Gyn
1100 West Morgan Street
Spencer, IN 47460

510(k) reference number: K983594

Device description:
The Embryo Transfer Catheter Sets are used for transferring IVF embryos into the uterine cavity. The materials used in these devices are Hytrel, Pellethane and stainless steel. Biocopatibility is assured.

Substantial Equivalence:
These devices will be manufactured according to specified controls and a Quality Assurance Program. These devices will undergo packaging nearly similar to the devices marketed by Cook OB/Gyn. Materials and physical construction are nearly similar to predicate devices, too. Being similar with respect to the indications for use to predicate devices, these devices meet the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Angelika Albrecht, Dipl.-Biol.
Safety Officer for Medical Devices
Labotect GmbH
Labor-Technik-Göttingen
Willi-Eichler-Straße 25
D37079 Göttingen
GERMANY

Re: K000950
Embryo Transfer Catheter Set
Model #320200 and 320201
Dated: March 1, 2000
Received: March 23, 2000
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQF

Dear Ms. Albrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): ~~Not yet assigned~~ K000950

Device Name: Embryo Transfer Catheter Set

Indications For Use:

The Embryo Transfer Catheter Set is used to place embryos into the uterine cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000950

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)